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March 30, 2004

Food and Drug Administration
Office of Device Evaluation
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Guidance Document Submission – Clinical Trial Design for Hip Replacement Systems

Ladies and Gentlemen:

Please find in triplicate, the enclosed above-referenced draft guidance submitted by the Orthopaedic Surgical Manufacturers Association (OSMA).

We look forward to any feedback you have prior to the Panel meeting where this document will be considered. If you have any questions in the meantime, please do not hesitate to contact Joel Batts at 813-877-4469.

Sincerely,

William Christianson
President, OSMA

BC/ejwg

Enclosure (3)

2003N-0561

C 1

ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION
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Clinical Trial Design for Hip Replacement Systems

INTRODUCTION

The purpose of this document is to propose a standardized method for designing clinical trials intended to measure the safety and efficacy of hip replacement systems (HRS). A standardized method of study design will provide a least burdensome approach to designing, reviewing, and acceptance of study protocols for both Sponsors and the FDA. The goal of the guidance is to provide consistency in the study design, review, and approval process and to speed up introduction of new devices to market. This document is not intended to address the reclassification of HRS devices. The terms “patient(s)” and “subject(s)” are used interchangeably throughout.

SCOPE

For the purpose of this document, an HRS is any device that is intended to replace the hip joint, in part or in total, as a treatment for joint disease, trauma, or dysfunction, where functional restoration and pain relief are the desired outcomes. HRS classifications include:

21 CFR 888.3353	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
21 CFR 888.3310	Hip joint metal/polymer constrained cemented or uncemented prosthesis
21 CFR 888.3320	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis
21 CFR 888.3330	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
21 CFR 888.3340	Hip joint metal/composite semi-constrained cemented prosthesis
21 CFR 888.3350	Hip joint metal/polymer semi-constrained cemented prosthesis
21 CFR 888.3358	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
21 CFR 888.3410	Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis
Not Classified	Hip joint metal/metal semi-constrained resurfacing cemented prosthesis (Device name - no description given in regulation)
Not Classified	Prosthesis, hip, semi-constrained, metal/polymer, uncemented (Device name - no description given in regulation)

CONSIDERATIONS FOR HRS CLINICAL STUDIES

Goals

The broad goal of clinical studies involving HRS is to generate safety and efficacy data for evaluating the use of HRS in treatment of damaged and diseased hip joints. Safety is defined on the basis of the number of adverse events relative to the number of subjects in

the study. Efficacy is defined on the basis of the extent to which function is restored and pain is relieved.

Variables

Other than HRS, few surgical options exist that both restore joint function and provide pain relief. Arthrodesis (fusion) may provide pain relief, but cannot restore joint function. Osteotomies around the hip joint may restore function and provide pain relief, yet the orientation of the joint surfaces are only shifted so that areas with less disease progression are in contact; the joint is not replaced.

HRS devices, on the other hand, have a clinically established, long-term record of safety and efficacy (see Appendices II and III). Sufficient information is available about the performance of these devices to allow for alternative study designs to randomized controlled trials. Because of this information and because of limitations in the other types of surgical treatment, safety and efficacy of new HRS devices are best established through comparison with other existing HRS devices.

This comparison should take place within the context of standardized measures for safety and efficacy, including at a minimum, *device-related complications, Harris Hip Scores (HHS), and revision surgeries.*

A. Device Related Complications

Complications are a measure of safety of the HRS device. All complications must be recorded, but only those possibly or probably related directly to the HRS should be included in the calculation (see Appendix IV).

Examples of device related complications include:

- Loss of function as might occur through subluxation or dislocation of the hip joint any time post-operatively.
- Excessive wear, migration, or breakage of any component of the HRS, even if such failure does not lead immediately to revision surgery **or** symptoms.

B. Harris Hip Score

The Harris Hip Score¹ has been the most widely used physician-generated scoring system in HRS studies in the United States. A rating of excellent, good, fair, or poor is generated based upon factors such as pain, range of motion, and ability to perform activities of daily living. The score reflects efficacy and correlates significantly with patient-derived scoring systems. Allowance can be made for using instruments other than HHS, but the sponsor must document comparability to the HHS and establish appropriate benchmarks.

¹ Harris W. JBJS(Am). 51-A(4):737-55. June 1969

C. Revision Surgeries

A revision is defined as a procedure that is performed on the replaced hip to remove and/or replace any component(s) that were implanted at the index operation. The percentage of revision surgeries should be calculated as the number of revisions divided by the number of subjects.

Standardized benchmarks

Disagreement exists within the orthopaedic community over what precisely constitutes a “successful” HRS patient outcome. On the one hand, objective measures, such as those obtained from analyzing device failures, can be used to assess safety of HRS components. On the other hand, subjective measures, such as pain severity, indicate the patient’s own assessment of the result of their HRS. Objective and subjective measures can produce contradicting depictions of HRS performance. Nonetheless, a combination of these two types of measures provides clinicians with the most comprehensive view of the success of the patient’s treatment.

Patient success

When quantitative values are applied to these variables, “patient success” can be determined. Patient success is attained when a subject meets the quantities defined in all variables. The standardized quantities for the variables are:

- A. Device related complications = 0 %
- B. HHS at 12 months greater or equal to 80
- C. Revision surgeries = 0 %

For secondary endpoint considerations, radiographic analysis should also be conducted. Measurements made on radiographs to determine implant position/migration are fairly standardized in the literature (e.g., Gruen zones and DeLee/Charnley zones). However, some HRS designs may not conform well to these measurement techniques. In such situations, the measurement techniques should be proposed by the Sponsor. In either case, the Sponsor should also propose the definition of “radiographic failure” and report the number of failures.

A quality of life measure may be used as well as a further measure of outcome, but is not required.

Study success

Based on the above criteria for patient success, each patient can be deemed either a “success” or “failure”. Study success is achieved when at least 95% of patients are deemed patient successes.

Number of subjects needed and data gathering intervals

In order to detect a difference between the HRS study device group and the 95% study success definition, the sample size should be no less than 239 subjects (see Appendix V). This number of subjects permits detection of any difference between the HRS device

study success and 95% study success definition, from 91% to 95%. In other words, this protocol is setup to indicate whether or not the HRS study device is at least within 4% of the 95% study success definition. Accordingly, the 95% C.I is 91.7% - 97.5% and the 90% C.I. is 90% - 97%.

Bilateral patients and attrition considerations may result in a different number of subjects needed depending on sponsor's device, indications for use, and overall goals of the study.

Data for HRS clinical studies should be gathered (at a minimum) preoperatively, at 6 weeks, 6 months and 12 months postoperatively.

Appendix I

Method of Defining Standardized Benchmarks

The development of standardized benchmarks was accomplished by clinical consensus. The consensus was determined by a group of orthopaedic surgeons specializing in hip replacement surgery. This group was assembled with the approval of the leadership and the members of the Hip Society. The Society exists to advance knowledge of the hip joint in health and in distress and to provide a forum to stimulate the exchange of knowledge concerning education, research, and treatment of disorders of the hip. The members of the team were:

William Bargar, MD	Joint Surgeons of Sacramento
Thomas Bauer, MD	Cleveland Clinic
David Blaha, MD	University of Michigan
Roger Emerson, MD	Private Practice, Plano, TX
Seth Greenwald, DPhil	Cleveland Clinic Health System
Michael Huo, MD	University of Kansas
Brian Kavanagh, MD	Private Practice, Greenwich, CT
Richard Kyle, MD	University of Minnesota
Adolph Lombardi, MD	Ohio State University
Michael Mont, MD	Johns Hopkins University
Philip Noble, PhD	Baylor College of Medicine
Steven Woolson, MD	Stanford University
Bernard Stulberg, MD	Cleveland Ct for Joint Reconstruction
Timothy Wright, PhD	Hospital for Special Surgery

This consensus team considered the 3 variables in the guidance document and reached conclusions on the minimum benchmark for each when determining “patient success”.

To aid the team in arriving at their conclusions, a literature search was performed aimed at discovering the failure modes of *total* hip replacement devices recorded in clinical studies of various HRS designs. The literature search was conducted using MeSH headings and sorted by the Levels of Evidence, described in Appendix II, as established by the Journal of Bone and Joint Surgery (Wright, et al. Vol. 85-A, 1-3, 2003). The sorted literature is shown in Appendix III.

The Team also compiled a comprehensive list of systemic and local (hip site) complications, described in Appendix IV. The Team also evaluated any other data within the articles that helped define the benchmarks.

The following questionnaire was used to facilitate the arrival at the benchmarks:

1. Please provide as comprehensive a list as possible of complications that can be attributed to HRS devices themselves.

2. What is the minimum acceptable change in Harris Hip Score at the final postoperative endpoint versus preoperative?
3. What is the minimum acceptable Harris Hip Score at the final postoperative endpoint?
4. What measures should be performed on postoperative radiographs and what are the minimum acceptable quantities of those measures?
5. What is the minimum percent difference in “clinical success” as defined in the draft guidance, between an HRS composite under study and the consensus benchmark composite?
6. What should the final postoperative endpoint be for HSR studies in terms of time?

Appendix II

Levels of Evidence for Primary Research Question

- | | |
|-----------|---|
| Level I | <ol style="list-style-type: none">1. Randomized controlled trial<ol style="list-style-type: none">a. Significant differenceb. No significant difference but narrow confidence intervals2. Systematic review ¹ of Level-I randomized controlled trials (studies were homogeneous) |
| Level II | <ol style="list-style-type: none">1. Prospective cohort study ²2. Poor-quality randomized controlled trial (e.g., <80% follow-up)3. Systematic review ¹<ol style="list-style-type: none">a. Level-II studiesb. nonhomogeneous Level-I studies |
| Level III | <ol style="list-style-type: none">1. Case-control study ³2. Retrospective cohort study ⁴3. Systematic review ¹ of Level-III studies |
| Level IV | Case series (no, or historical, control group) |
| Level V | Expert opinion |
1. A study of results from two or more previous studies. The study was initiated after treatment was performed
 2. Patients were compared with a control group of patients treated at the same time and institution.
 3. Patients with a particular outcome ("cases" with, for example, a failed total arthroplasty) were compared with those who did not have the outcome ("controls" with, for example, a total hip arthroplasty that did not fail).
 4. The study was initiated after treatment was performed.

Appendix III

Literature Review for Hip Studies Guidance Document

A. JBJS Level of Evidence I

Search strategy – Limits: English language publications, MeSH terms “Arthroplasty”, “Replacement” and “Hip”, Randomized Control Trials

Results: 246 citations found; exclusion criteria are any articles that are not using prosthesis/patient outcome as primary variable (i.e., articles looking at different DVT prophylaxis drugs, different preoperative education techniques, etc.)

- 1: Kim YH, Oh SH, Kim JS, Koo KH. Contemporary total hip arthroplasty with and without cement in patients with osteonecrosis of the femoral head. *J Bone Joint Surg Am*. 2003 Apr;85-A(4):675-81.
PMID: 12672844 [PubMed - indexed for MEDLINE]
- 2: MacDonald SJ, McCalden RW, Chess DG, Bourne RB, Rorabeck CH, Cleland D, Leung F. Metal-on-metal versus polyethylene in hip arthroplasty: a randomized clinical trial. *Clin Orthop*. 2003 Jan;(406):282-96.
PMID: 12579029 [PubMed - indexed for MEDLINE]
- 3: D'Antonio J, Capello W, Manley M. Alumina ceramic bearings for total hip arthroplasty. *Orthopedics*. 2003 Jan;26(1):39-46.
PMID: 12555833 [PubMed - indexed for MEDLINE]
- 4: Laupacis A, Bourne R, Rorabeck C, Feeny D, Tugwell P, Wong C. Comparison of total hip arthroplasty performed with and without cement : a randomized trial. *J Bone Joint Surg Am*. 2002 Oct;84-A(10):1823-8.
PMID: 12377914 [PubMed - indexed for MEDLINE]
- 5: Pitto RP, Blanquaert D, Hohmann D. Alternative bearing surfaces in total hip arthroplasty: zirconia-alumina pairing. Contribution or caveat? *Acta Orthop Belg*. 2002 Jun;68(3):242-50.
PMID: 12152371 [PubMed - indexed for MEDLINE]
- 6: Rasquinha VJ, Ranawat CS, Mauriello AJ Jr. Hydroxyapatite: catalyst or conjuror? *J Arthroplasty*. 2002 Jun;17(4 Suppl 1):113-7.
PMID: 12068419 [PubMed - indexed for MEDLINE]
- 7: D'Antonio J, Capello W, Manley M, Bierbaum B. New experience with alumina-on-alumina ceramic bearings for total hip arthroplasty. *J Arthroplasty*. 2002 Jun;17(4):390-7.
PMID: 12066265 [PubMed - indexed for MEDLINE]

- 8: Settecce JJ, Kelley SS, Rand JA, Fitzgerald RH Jr. Collar versus collarless cemented HD-II femoral prostheses. Clin Orthop. 2002 May;(398):146-52.
PMID: 11964644 [PubMed - indexed for MEDLINE]
- 9: Lombardi AV Jr, Mallory TH, Alexiades MM, Cuckler JM, Faris PM, Jaffe KA, Keating EM, Nelson CL Jr, Ranawat CS, Williams J, Wixson R, Hartman JF, Capps SG, Kefauver CA. Short-term results of the M2a-taper metal-on-metal articulation. J Arthroplasty. 2001 Dec;16(8 Suppl 1):122-8.
PMID: 11742463 [PubMed - indexed for MEDLINE]
- 10: Tanzer M, Kantor S, Rosenthal L, Bobyn JD. Femoral remodeling after porous-coated total hip arthroplasty with and without hydroxyapatite-tricalcium phosphate coating: a prospective randomized trial. J Arthroplasty. 2001 Aug;16(5):552-8.
PMID: 11503113 [PubMed - indexed for MEDLINE]
- 11: Sharp RJ, O'Leary ST, Falworth M, Cole A, Jones J, Marshall RW. Analysis of the results of the C-Fit uncemented total hip arthroplasty in young patients with hydroxyapatite or porous coating of components. J Arthroplasty. 2000 Aug;15(5):627-34. Review.
PMID: 10960002 [PubMed - indexed for MEDLINE]
- 12: Thanner J, Karrholm J, Herberts P, Malchau H. Hydroxyapatite and tricalcium phosphate-coated cups with and without screw fixation: a randomized study of 64 hips. J Arthroplasty. 2000 Jun;15(4):405-12.
PMID: 10884197 [PubMed - indexed for MEDLINE]
- 13: Yee AJ, Kreder HK, Bookman I, Davey JR. A randomized trial of hydroxyapatite coated prostheses in total hip arthroplasty. Clin Orthop. 1999 Sep;(366):120-32.
PMID: 10627726 [PubMed - indexed for MEDLINE]
- 14: Garellick G, Malchau H, Regner H, Herberts P. The Charnley versus the Spectron hip prosthesis: radiographic evaluation of a randomized, prospective study of 2 different hip implants. J Arthroplasty. 1999 Jun;14(4):414-25.
PMID: 10428221 [PubMed - indexed for MEDLINE]
- 15: Garellick G, Malchau H, Herberts P. The Charnley versus the Spectron hip prosthesis: clinical evaluation of a randomized, prospective study of 2 different hip implants. J Arthroplasty. 1999 Jun;14(4):407-13.
PMID: 10428220 [PubMed - indexed for MEDLINE]
- 16: Meding JB, Ritter MA, Keating EM, Faris PM, Edmondson K. A comparison of collared and collarless femoral components in primary cemented total hip arthroplasty: a randomized clinical trial. J Arthroplasty. 1999 Feb;14(2):123-30.
PMID: 10065715 [PubMed - indexed for MEDLINE]

17: Bourne RB, Rorabeck CH. A critical look at cementless stems. Taper designs and when to use alternatives. Clin Orthop. 1998 Oct;(355):212-23.
PMID: 9917606 [PubMed - indexed for MEDLINE]

18: Kelley SS, Lachiewicz PF, Hickman JM, Paterno SM. Relationship of femoral head and acetabular size to the prevalence of dislocation. Clin Orthop. 1998 Oct;(355):163-70.
PMID: 9917601 [PubMed - indexed for MEDLINE]

19: Middleton RG, Howie DW, Costi K, Sharpe P. Effects of design changes on cemented tapered femoral stem fixation. Clin Orthop. 1998 Oct;(355):47-56.
PMID: 9917590 [PubMed - indexed for MEDLINE]

20: Incavo SJ, Schneider R, Elting J. The effect of surface coating of femoral prostheses implanted without cement: a 2- to 4-year follow-up study. Am J Orthop. 1998 May;27(5):355-61.
PMID: 9604107 [PubMed - indexed for MEDLINE]

21: D'Lima DD, Oishi CS, Petersilge WJ, Colwell CW Jr, Walker RH. 100 cemented versus 100 noncemented stems with comparison of 25 matched pairs. Clin Orthop. 1998 Mar;(348):140-8.
PMID: 9553546 [PubMed - indexed for MEDLINE]

22: Onsten I, Carlsson AS, Besjakov J. Wear in uncemented porous and cemented polyethylene sockets: a randomised, radiostereometric study. J Bone Joint Surg Br. 1998 Mar;80(2):345-50.
PMID: 9546474 [PubMed - indexed for MEDLINE]

B. JBJS Levels of Evidence II or III

Search strategy – Limits: English language publications, MeSH terms “Arthroplasty”, “Replacement”, “Hip”, and “Cohort Studies”

Results: 970 citations found; exclusion criteria are any articles that are not using prosthesis/patient outcome as primary variable (ie, articles looking at different DVT prophylaxis drugs, different preoperative education techniques, etc.)

[Still reviewing the results list for this search. 260 citations searched thus far.]

1: Jacobsen S, Jensen FK, Poulsen K, Sturup J, Retpen JB. Good performance of a titanium femoral component in cementless hip arthroplasty in younger patients: 97 arthroplasties followed for 5-11 years. Acta Orthop Scand. 2003 Jun;74(3):248-52. No abstract available.
PMID: 12899542 [PubMed - indexed for MEDLINE]

2: Reikeras O, Gunderson RB. Excellent results of HA coating on a grit-blasted stem: 245 patients followed for 8-12 years. Acta Orthop Scand. 2003 Apr;74(2):140-5.
PMID: 12807319 [PubMed - indexed for MEDLINE]

3: Bojescul JA, Xenos JS, Callaghan JJ, Savory CG. Results of porous-coated anatomic total hip arthroplasty without cement at fifteen years: a concise follow-up of a previous report. J Bone Joint Surg Am. 2003 Jun;85-A(6):1079-83.
PMID: 12784006 [PubMed - indexed for MEDLINE]

4: Keener JD, Callaghan JJ, Goetz DD, Pederson DR, Sullivan PM, Johnston RC. Twenty-five-year results after Charnley total hip arthroplasty in patients less than fifty years old: a concise follow-up of a previous report. J Bone Joint Surg Am. 2003 Jun;85-A(6):1066-72.
PMID: 12784004 [PubMed - indexed for MEDLINE]

5: Skinner JA, Kroon PO, Todo S, Scott G. A femoral component with proximal HA coating. An analysis of survival and fixation at up to ten years. J Bone Joint Surg Br. 2003 Apr;85(3):366-70.
PMID: 12729111 [PubMed - indexed for MEDLINE]

6: Pieringer H, Auersperg V, Griessler W, Bohler N. Long-term results with the cementless Alloclassic brand hip arthroplasty system. J Arthroplasty. 2003 Apr;18(3):321-8.
PMID: 12728424 [PubMed - indexed for MEDLINE]

7: Meneghini RM, Feinberg JR, Capello WN. Primary hybrid total hip arthroplasty with a roughened femoral stem: integrity of the stem-cement interface. J Arthroplasty. 2003 Apr;18(3):299-307.
PMID: 12728421 [PubMed - indexed for MEDLINE]

8: Capello WN, D'Antonio JA, Feinberg JR, Manley MT. Ten-year results with hydroxyapatite-coated total hip femoral components in patients less than fifty years old. A concise follow-up of a previous report. J Bone Joint Surg Am. 2003 May;85-A(5):885-9.
PMID: 12728040 [PubMed - indexed for MEDLINE]

9: Aldinger PR, Breusch SJ, Lukoschek M, Mau H, Ewerbeck V, Thomsen M. A ten- to 15-year follow-up of the cementless spotorno stem. J Bone Joint Surg Br. 2003 Mar;85(2):209-14.
PMID: 12678354 [PubMed - indexed for MEDLINE]

10: Kim YH, Oh SH, Kim JS, Koo KH. Contemporary total hip arthroplasty with and without cement in patients with osteonecrosis of the femoral head. J Bone Joint Surg Am. 2003 Apr;85-A(4):675-81.
PMID: 12672844 [PubMed - indexed for MEDLINE]

11: Franklin J, Robertsson O, Gestsson J, Lohmander LS, Ingvarsson T. Revision and complication rates in 654 Exeter total hip replacements, with a maximum follow-up of 20 years. BMC Musculoskelet Disord. 2003 Mar 25;4(1):6.
PMID: 12659648 [PubMed - indexed for MEDLINE]

12: Floren M, Lester DK. Outcomes of total hip arthroplasty and contralateral bipolar hemiarthroplasty: a case series. J Bone Joint Surg Am. 2003 Mar;85-A(3):523-6. No abstract available.

PMID: 12637441 [PubMed - indexed for MEDLINE]

13: Epinette JA, Manley MT, D'Antonio JA, Edidin AA, Capello WN. A 10-year minimum follow-up of hydroxyapatite-coated threaded cups: clinical, radiographic and survivorship analyses with comparison to the literature. J Arthroplasty. 2003 Feb;18(2):140-8.

PMID: 12629602 [PubMed - indexed for MEDLINE]

14: Korovessis P, Petsinis G, Repanti M. Zweymueller with metal-on-metal articulation: clinical, radiological and histological analysis of short-term results. Arch Orthop Trauma Surg. 2003 Feb;123(1):5-11. Epub 2002 Dec 19.

PMID: 12582789 [PubMed - indexed for MEDLINE]

15: Garcia-Cimbrelo E, Cruz-Pardos A, Madero R, Ortega-Andreu M. Total hip arthroplasty with use of the cementless Zweymuller Alloclassic system. A ten to thirteen-year follow-up study. J Bone Joint Surg Am. 2003 Feb;85-A(2):296-303.

PMID: 12571308 [PubMed - indexed for MEDLINE]

16: Katsimihis M, Taylor AH, Lee MB, Sarangi PP, Learmonth ID. Cementless acetabular replacement in patients with rheumatoid arthritis: a 6- to 14-year prospective study. J Arthroplasty. 2003 Jan;18(1):16-22.

PMID: 12555177 [PubMed - indexed for MEDLINE]

17: Lachiewicz PF, Messick P. Precoated femoral component in primary hybrid total hip arthroplasty: results at a mean 10-year follow-up. J Arthroplasty. 2003 Jan;18(1):1-5.

PMID: 12555174 [PubMed - indexed for MEDLINE]

18: Phillips CB, Barrett JA, Losina E, Mahomed NN, Lingard EA, Guadagnoli E, Baron JA, Harris WH, Poss R, Katz JN. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. J Bone Joint Surg Am. 2003 Jan;85-A(1):20-6.

PMID: 12533567 [PubMed - indexed for MEDLINE]

19: Engh CA Jr, Ellis TJ, Koralewicz LM, McAuley JP, Engh CA Sr. Extensively porous-coated femoral revision for severe femoral bone loss: minimum 10-year follow-up. J Arthroplasty. 2002 Dec;17(8):955-60.

PMID: 12478503 [PubMed - indexed for MEDLINE]

20: Teloken MA, Bissett G, Hozack WJ, Sharkey PF, Rothman RH. Ten to fifteen-year follow-up after total hip arthroplasty with a tapered cobalt-chromium femoral component (tri-lock) inserted without cement. J Bone Joint Surg Am. 2002 Dec;84-A(12):2140-4.

PMID: 12473700 [PubMed - indexed for MEDLINE]

- 21: Meek RM, Michos J, Grigoris P, Hamblen DL. Mid-term results and migration behaviour of a ti-alloy cemented stem. *Int Orthop*. 2002;26(6):356-60. Epub 2002 Jul 17. PMID: 12466868 [PubMed - indexed for MEDLINE]
- 22: Healy WL, Casey DJ, Iorio R, Appleby D. Evaluation of the porous-coated anatomic hip at 12 years. *J Arthroplasty*. 2002 Oct;17(7):856-63. PMID: 12375243 [PubMed - indexed for MEDLINE]
- 23: Mann CJ, McNally S, Taylor E, Shepperd JA. A retrospective clinical and radiographic review of 173 hydroxyapatite-coated screw cups with 5- to 10-year follow-up, showing low revision rates for fixation failure. *J Arthroplasty*. 2002 Oct;17(7):851-5. PMID: 12375242 [PubMed - indexed for MEDLINE]
- 24: Kim YH. Cementless total hip arthroplasty with a close proximal fit and short tapered distal stem (third-generation) prosthesis. *J Arthroplasty*. 2002 Oct;17(7):841-50. PMID: 12375241 [PubMed - indexed for MEDLINE]
- 25: Roy N, Hossain S, Ayeko C, McGee HM, Elsworth CF, Jacobs LG. 3M Capital hip arthroplasty: 3-8-year follow-up of 208 primary hip replacements. *Acta Orthop Scand*. 2002 Aug;73(4):400-2. PMID: 12358111 [PubMed - indexed for MEDLINE]
- 26: Brown SR, Davies WA, DeHeer DH, Swanson AB. Long-term survival of McKee-Farrar total hip prostheses. *Clin Orthop*. 2002 Sep;(402):157-63. PMID: 12218479 [PubMed - indexed for MEDLINE]
- 27: Sanchez-Sotelo J, Berry DJ, Harmsen S. Long-term results of use of a collared matte-finished femoral component fixed with second-generation cementing techniques. A fifteen-year-median follow-up study. *J Bone Joint Surg Am*. 2002 Sep;84-A(9):1636-41. PMID: 12208922 [PubMed - indexed for MEDLINE]
- 28: Lai KA, Shen WJ, Chen CH, Yang CY, Hu WP, Chang GL. Failure of hydroxyapatite-coated acetabular cups. Ten-year follow-up of 85 Landos Atoll arthroplasties. *J Bone Joint Surg Br*. 2002 Jul;84(5):641-6. PMID: 12188477 [PubMed - indexed for MEDLINE]
- 29: Fyda TM, Callaghan JJ, Olejniczak J, Johnston RC. Minimum ten-year follow-up of cemented total hip replacement in patients with osteonecrosis of the femoral head. *Iowa Orthop J*. 2002;22:8-19. PMID: 12180617 [PubMed - indexed for MEDLINE]
- 30: Jergesen HE, Karlen JW. Clinical outcome in total hip arthroplasty using a cemented titanium femoral prosthesis. *J Arthroplasty*. 2002 Aug;17(5):592-9. PMID: 12168175 [PubMed - indexed for MEDLINE]

31: Emerson RH Jr, Head WC, Emerson CB, Rosenfeldt W, Higgins LL. A comparison of cemented and cementless titanium femoral components used for primary total hip arthroplasty: a radiographic and survivorship study. J Arthroplasty. 2002 Aug;17(5):584-91.

PMID: 12168174 [PubMed - indexed for MEDLINE]

32: Hsieh PH, Shih CH, Lee PC, Chen CH, Yang WE. Primary total hip arthroplasty without the use of bone cement: a 10-year follow-up of 157 hips. Chang Gung Med J. 2002 May;25(5):298-305.

PMID: 12141702 [PubMed - indexed for MEDLINE]

33: Ravasi F, Sansone V. Five-year follow-up with a ceramic sandwich cup in total hip replacement. Arch Orthop Trauma Surg. 2002 Jul;122(6):350-3. Epub 2002 Feb 02.

PMID: 12136301 [PubMed - indexed for MEDLINE]

34: Udomkiat P, Dorr LD, Wan Z. Cementless hemispheric porous-coated sockets implanted with press-fit technique without screws: average ten-year follow-up. J Bone Joint Surg Am. 2002 Jul;84-A(7):1195-200.

PMID: 12107321 [PubMed - indexed for MEDLINE]

35: Wingstrand I, Persson BM, Wingstrand H. Total hip replacement with second generation cementing technique and the monobloc ScanHip: a 10-year follow-up. Int Orthop. 2002;26(2):69-71.

PMID: 12078879 [PubMed - indexed for MEDLINE]

36: Benko TZ, Santiago-Martin A, Ruddlesdin C, Selzer G. Aseptic loosening of 2 rim-fix, hydroxyapatite-coated acetabular cups. J Arthroplasty. 2002 Jun;17(4):519-23.

PMID: 12066288 [PubMed - indexed for MEDLINE]

37: Khalily C, Lester DK. Results of a tapered cementless femoral stem implanted in varus. J Arthroplasty. 2002 Jun;17(4):463-6.

PMID: 12066277 [PubMed - indexed for MEDLINE]

38: Kim YH. Bilateral cemented and cementless total hip arthroplasty. J Arthroplasty. 2002 Jun;17(4):434-40.

PMID: 12066272 [PubMed - indexed for MEDLINE]

39: Trudelle-Jackson E, Emerson R, Smith S. Outcomes of total hip arthroplasty: a study of patients one year postsurgery. J Orthop Sports Phys Ther. 2002 Jun;32(6):260-7.

PMID: 12061707 [PubMed - indexed for MEDLINE]

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C. JBJS Levels of Evidence IV or V

**Search strategy – Limits: English language publications, MeSH terms
“Arthroplasty”, “Replacement” and “Hip”, Publication type – Literature reviews,
tutorial reviews**

**Results: 307 citations found; exclusion criteria are any articles that are not using
prosthesis/patient outcome as primary variable (ie, articles looking at different
DVT prophylaxis drugs, different preoperative education techniques, etc.) or those
that do not discuss complications associated with the prosthesis.**

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Appendix IV

Complications

Complications	Number found	Percent of total	Code
Dislocation	300	20.15	3
Femoral bone fracture - intraop	253	16.99	3
DVT	149	10.01	4
Pulmonary embolism	112	7.52	4
Femoral, greater troch osteotomy nonunion	64	4.30	1
UTI	58	3.90	4
Osteolysis - femur and/or acetabulum	56	3.76	2
Loosening, fem and/or acet component, septic or aseptic	52	3.49	3
Pain, thigh	44	2.96	3, 4
Infection, non-descript	42	2.82	1
Leg length discrepancy	34	2.28	1
Pain, non-descript	34	2.28	4
Infection, deep	26	1.75	4
Cardiovascular complications	25	1.68	4
Peroneal nerve palsy	24	1.61	1
Heterotopic ossification	23	1.54	1, 4
Femoral, greater troch fracture - intraop	17	1.14	1
Acetabular ceramic liner chipped - intraop	16	1.07	3
Sciatic nerve palsy	14	0.94	1
Femoral calcar fracture - intraop	13	0.87	3
Femoral nerve palsy	13	0.87	1
Neuropathy, non-descript	13	0.87	1, 4
Infection, superficial infection	12	0.81	1, 4
Hematoma	11	0.74	4
Femoral periprosthetic fracture	9	0.60	3
Gout	7	0.47	4
Urinary retention	7	0.47	4
Acetabular malposition - intraop	6	0.40	1
Pneumonia	6	0.40	4
Wound, delayed healing	6	0.40	1, 4
Femoral wall perforation - intraop	5	0.34	1
Wound drainage	5	0.34	1, 4
Acetabular liner dissociation	3	0.20	2
Acetabular wall perforation - intraop	3	0.20	3, 1
Femoral component subsidence	3	0.20	3
Intestinal ileus	3	0.20	4, 1
Acetabular ceramic liner fracture	2	0.13	2
Acetabular liner/head eccentricity	2	0.13	2
Enterocolitis	2	0.13	4
Acetabular poly liner fracture	1	0.07	2
Bursitis	1	0.07	4

Cholecystitis	1	0.07	4
Diarrhea	1	0.07	4
Femoral component fracture	1	0.07	2
Hepatitis	1	0.07	4
Impingement	1	0.07	3
Inguinal abscess	1	0.07	4
Jaundice	1	0.07	4
Leukaemic crisis	1	0.07	4
Metallosis - screw/screw contact	1	0.07	2
Paralytic ileus	1	0.07	4
Peptic ulcer	1	0.07	4
Seizure	1	0.07	4
Subluxation	1	0.07	3
TOTALS	1489	100	

Code Key	Description	Code
1		Op technique only
2		Implant only
3		Op tech and implant
4		Systemic/unrelated
5		Other

The codes in the last column indicate the Clinician Team's judgment as to the general etiology of the complication. This was done in order to attribute the complication so that safety of the HRS device could be properly evaluated. Based on the coding system only complications designated as 2 or 3 would be deemed as possibly or probably device related.

Appendix V

Power Calculation

The following is the power calculation used on page 3 of this document:

Bioequivalence

Desired rate is 95%.

Alpha is set to 0.05, one outcome.

Observed rate 90%.

235 cases, gives a rate of 0.90 with a 95% C.I. of 85% - 93%, and a power of 0.8.

Observed rate 93%.

235 cases gives a rate of 0.93 with a 95% C.I. of 89% - 96%, and a power of 0.9.